



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/711,961	09/06/96	BRANSTROM	A 003/030/SAR

MCGR-JA (JOHN MORAN)
US ARMY MEDICAL RESEARCH
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16N2/0429

VOGEL, N

ART UNIT	PAPER NUMBER
1805	

DATE MAILED: 04/29/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/711,961	Applicant(s) Branstrom et al.
	Examiner Nancy T. Vogel	Group Art Unit 1805

Responsive to communication(s) filed on Feb 10, 1997

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-44 is/are pending in the application.

Of the above, claim(s) 1-27 and 34-43 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 28-33 and 44 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1805

1. Claims 1-27 and 34-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 6.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Sansonetti et al. (PR on 1449 form).

Sansonetti et al. disclose a method for the delivery of functional nucleic acids into a cell using bacteria comprising introducing said nucleic acids into an attenuated (non-virulent) bacteria, and administering said bacteria to a cell (see abstract, Tables 3 and 4, and page 1399).

3. Claim 44 is rejected under 35 U.S.C. 102(e) as being anticipated by Brey et al. (U.S. Pat. No. 5,112,749) (A).

Brey et al. disclose a method for the delivery of functional nucleic acids into a cell using bacteria comprising introducing said nucleic acids into an attenuated (non-virulent) bacteria, and administering said bacteria to a cell (see abstract).

Art Unit: 1805

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 28, 29, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brey et al. (U.S. Pat. No. 5,112,749) (A).

Brey et al. disclose a method for delivering DNA to a cell, said method comprising introducing said DNA into attenuated *Salmonella*, and administering said *Salmonella* to said cell. The cell is mucosal epithelium. The difference between the reference and the instant claims is that *Shigella* strains are used.

However, Brey et al. discloses that attenuated *Shigella* strains may also be used in the same method as set forth above (see col. 19, lines 15-48, abstract and claims). It would have been obvious to one of ordinary skill in the art to have substituted *Shigella* strains for the

Art Unit: 1805

Salmonella strain in the method disclosed by Brey et al., in view of the teaching in Brey that Shigella may be utilized for its known and useful properties in the disclosed method.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brey et al. (U.S. Pat. No. 5,112,749) (A) as applied to claims 28, 29, 31-33 above, and further in view of Curtiss et al. (U.S. Pat. No. 4,888,170) (B) or Curtiss et al. (5,468,485) (C).

Brey et al. is applied for the reasons set forth in the above rejection. The difference between the reference and the instant claim is that a specific attenuated Shigella strain which is asd- is utilized.

However, Curtiss et al. (4888170) and Curtiss et al. (5,468,485) disclose the use of the asd mutation to render a virulent bacteria attenuated (see col. 9 and col. 3, respectively). It would have been obvious to one of ordinary skill in the art to have utilized an asd- strain of Shigella as an attenuated strain in the method disclosed by Brey et al., since such mutations were known in the art to cause attenuation, as evidenced by Curtiss '170 and Curtiss '485.a.

8. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In view of the nature of the biological material, it is unclear if the disclosure is sufficiently repeatable to avoid the need of a deposit. Further, it is unclear if the disclosure

Art Unit: 1805

alone is sufficient to provide an enabling disclosure because it is unknown if the starting materials were readily available to the public at the time of the invention. Therefore, a deposit is required.

The deposit must meet all the criteria set forth in 37 CFR 1.801-1.809 (See attachment entitled "Suggestion for Deposit of Biological Material").

9. Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 is vague and indefinite in the recitation of "functional nucleic acids". It is not clear what is intended by this phrase.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-0278. The examiner can normally be reached on Monday through Wednesday from 7:30AM to 3:00PM.

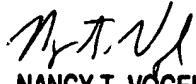
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-0407. Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. Papers should be faxed to Art Unit 1805 via the PTO FAX Center located in Crystal Mall 1. The faxing of such papers must conform with

Art Unit: 1805

the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1805 FAX number is (703) 308-0294.

NOTE: If Applicants **does submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.**

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



NANCY T. VOGEL
PRIMARY EXAMINER
GROUP 1800

Serial Number: 08/711,961

Page 7

Art Unit: 1805

ATTACHMENT

ATTACHMENT

ATTACHMENT

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

[C.F.R. § 1.801 - 1.809]

A declaration or statement by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent.
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, and the complete taxonomic description.